CRYO.TAS

MEDICAL GASES

CRYOGENIC-GASES TERMINAL AUTOMATION SYSTEM

DESCRIPTION

Medical gases are an important part of the gas industry and subject to strict requirements in production, monitoring and sales. CRYO.TAS includes all the necessary prerequisites for storage, batch formation, transport and traceability of the medical products. All requirements from the underlying regulations and authority specifications are met.

Thus, CRYO.TAS includes all functions and prerequisites from the EG-GMP guideline parts I and II.

The measures for compliance with the specifications are not only part of the system software, but also include all system parts.

Additionally, the system can be expanded by the function of electronic release (add-on module). This module was developed in cooperation with the authorities to simplify the release processes of batches and effective substances, execute them independently of location and document them comprehensively.

The present scope of functions for the medical gases can also be used for other special products.

BENEFITS

- Seamless documentation of all processes
- Audit trail
- Automatic batch formation
- Generation of effective substance protocols
- Automatic notification of the release authorities
- Recording the OOS-results
- Add-on for release of medical batches independently of location
- Recording all results in release tabs
- Electronic 4-eye principle
- Maximum process safety

MEASURES AND SPECIAL FUNCTIONS FOR MEDICAL GASES

SYSTEM ADMINISTRATION

- Electronic 4-eye principle:
  If there are any changes to medical products or any system components used for them, confirmation by another qualified person is required.
- Electronic release process (add-on):
  Reporting batches to be released to the relevant persons via email (QP).
  Remote review of the results and remote release with inspection of the release sequence.
  Documentation of all release steps in the release tabs
- Own QP area in the system operation:
  Definition of operating limitations for the specifications of medical products or changes to relevant system components.
- Approval Archive:
  Archiving of all release steps with comments in the release archive.

LOADING POINTS

- Release of a loading point for loading of medical products only.

VEHICLES

- Definition of rights for loading medical products for transport containers.

DRIVER AND OPERTING STAFF

- Assessment type of medical products.
- Review for trainings performed and approvals for handling of medical products (e.g. hygiene training)

BATCH FORMATION

- Support of common batch formation for:
  - Real batch tank with finished medical product loading from batch tank
  - Continuous storage tank: Formation of an effective substance batch with effective substance loading. Then formation of the finished medical product in the transport container.

LOCKING MED. PRODUCTS

- Automatic lock at:
  - Unauthorized opening of valves at the batch tank.
  - Non-performance of the specification at cyclic tank test (only continuous storage tank).
  - Change to a product specification of a medical product.
  - Change of a function parameter that is marked as "quality relevant" for medical products.
  - Defective or incorrect test equipment for monitoring medical products.

GENERAL SYSTEM FUNCTIONS

- Transport container identification by RFID transponder
- Person identification by RFID transponder
- 1:1 assignment of loading point and analysis point. This precludes swapping of transport tanks.

VALIDATION CAPACITY

- System development and expansions are generally performed according to the V model purs. to GMP.
- EG-GMP parts I and II; EC-GMP Appendix 6 compliant
- Service and support contracts contain the service of "Change management" for your entire system installation.
- Compliance with all directives and specifications for a possible system validation

OPERATING INTERFACE QP-AREA

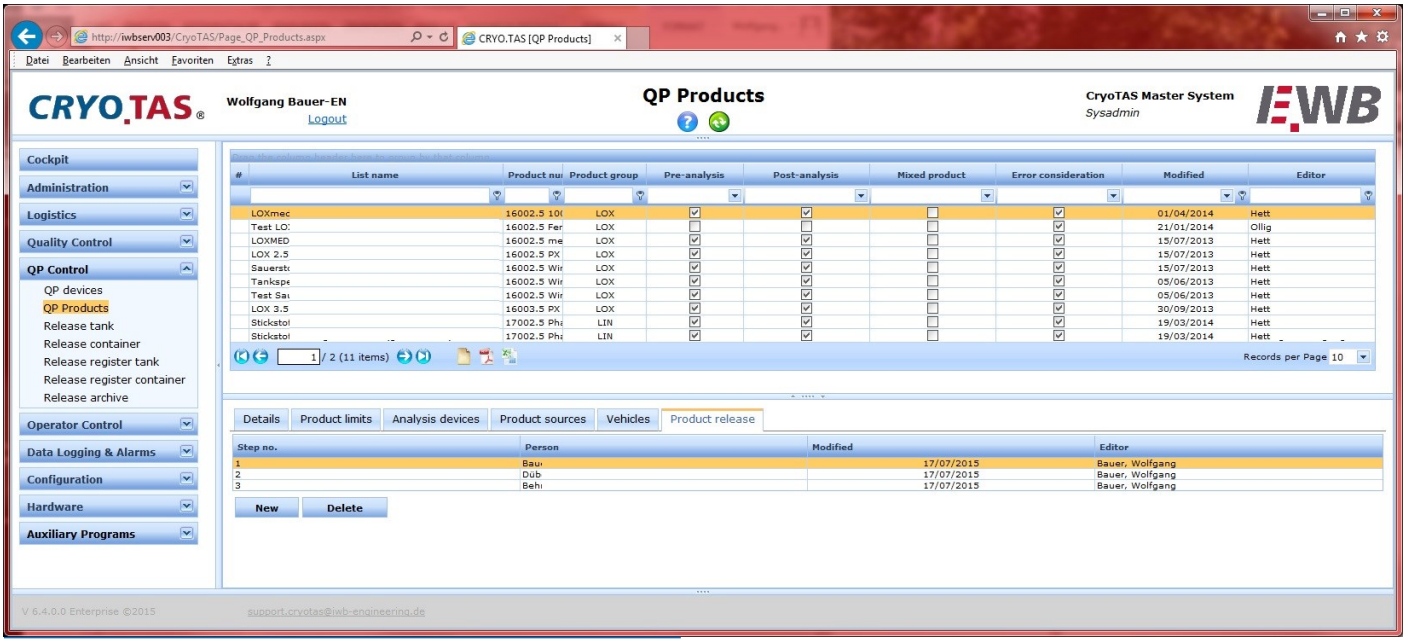


FIG.: QP-PRODUCTS

Definition of the release steps for the electronic release in the QP area for the administration of the medical products.

Any number of release steps can be defined for a medical product. The order of the releases is defined with the step number. After formation of a batch of a product with release steps, the persons entered in the product release are automatically informed about the required release process. The releases can only be performed in the specified order. Every person must authenticate individually for the release process.

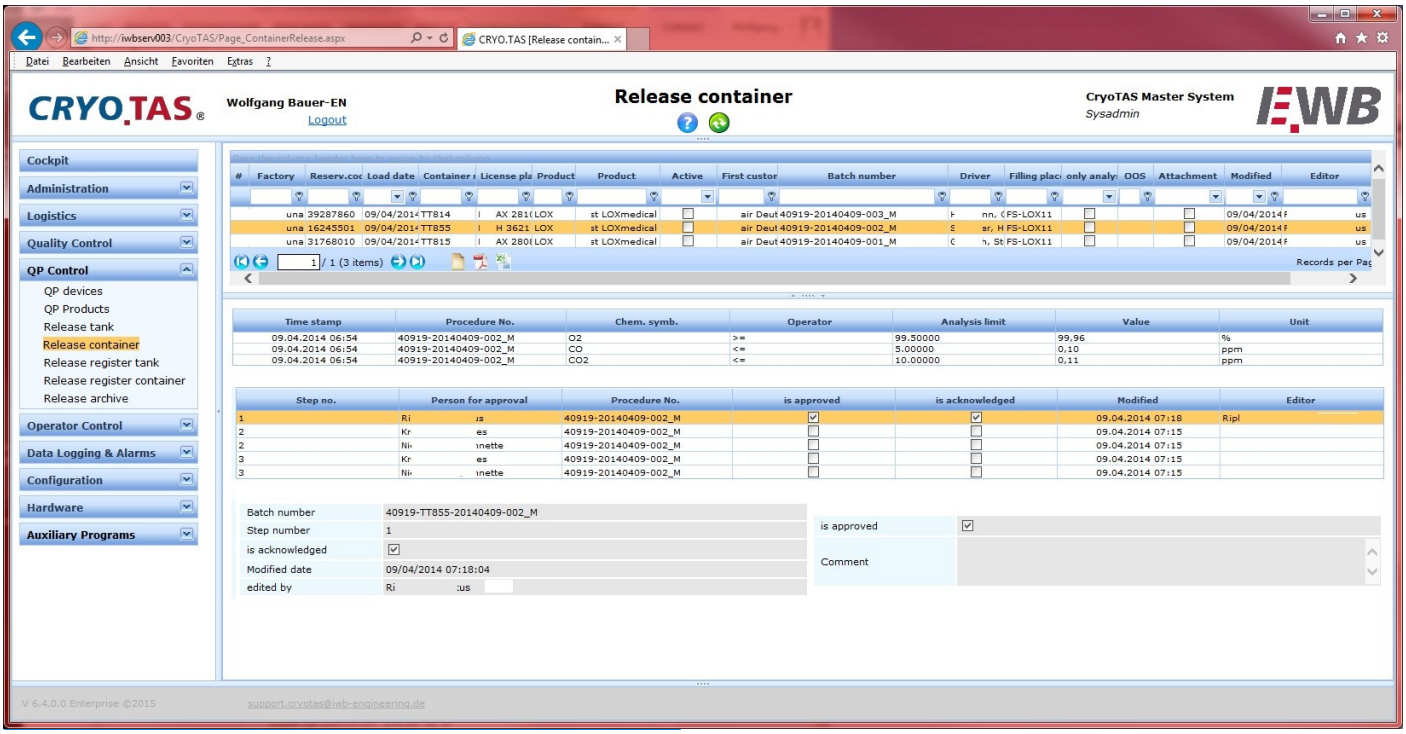


FIG.: RELEASE VEHICLE

Example of a vehicle release after loading in the transport container. The release step no. 1, head of production, has already been performed.

After processing of the last release step, the system will automatically generate the effective substance log.

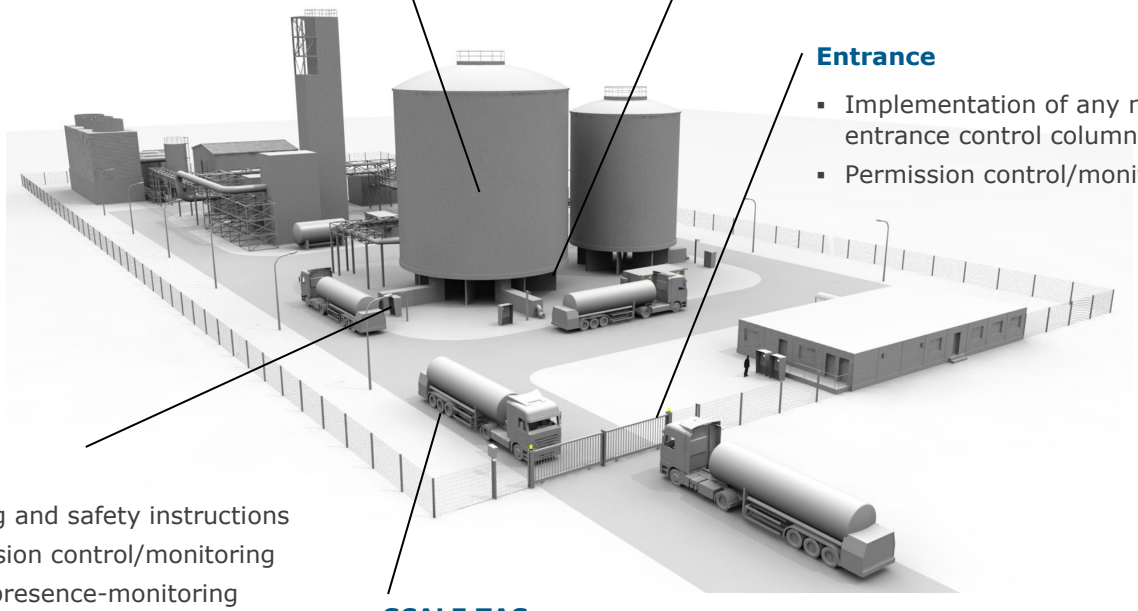
CRYO.TAS THE OVERALL CONCEPT

Tank-Management

- Product availability monitoring
- Lock and unlock of products
- Batch creation
- Special functions for medical– and food-products
- Calculation of loaded quantities

Analysis

- Automated gas path switching
- Test equipment– and calibration gas monitoring
- Auto-calibration
- Locking and unlocking of test equipment
- Connectivity to a wide range of sample point types (e.g. pipeline)



Entrance

- Implementation of any number of entrance control columns
- Permission control/monitoring

Loading

- Loading and safety instructions
- Permission control/monitoring
- Force-presence-monitoring
- Quality assurance/analysis
- Blending functionality
- Off-loading
- Special functions for medical products
- Control of all field devices

SCALE.TAS

- Usage of any number of weigh bridges
- Free usage of entry– or exit weigh bridge, or both
- Creation of loading/transportation documents
- Quota control

INFORMATION

Would you like more information about the CRYO.TAS system? On the Internet you always get the latest information, or contact us directly. We are always ready to show you the performance of the system in a live presentation.

Simply contact:

IWB
Alte Toelzerstr. 7
82544 Egling/OT Deining
Germany
Tel: +49 (0) 8170 925 277
Fax:+49 (0) 8170 996 9250
Contact: info@iwb-engineering.de